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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/835,920	04/10/97	CHENG S	970232/HG

12M2/1021

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EXAMINER	
HENLEY III,R	
ART UNIT	**PAPER NUMBER**
1205	

DATE MAILED: 10/21/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary

Application No.	Applicant(s)
08/835,920	Shu Jun Cheng, et al.
Examiner	**Group Art Unit**
Ray Henley	1205

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

CLAIMS 1-8 ARE PRESENTED FOR EXAMINATION

Claim Rejection - 35 USC § 112

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 (line 2) and claim 8 (line 3), the expression "comprises containing" is unclear. The subject matter of claims 4 and 8 is also indefinite because the word "capsule" has no antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by applicants' acknowledgment of Polyphenon 100™ or Polyphenon E™ at pages 3-4 of the present specification. The expression "for a treatment of HPV-infected Condyloma acuminata" in claim 1

is noted, but does not impart any material characteristic to the claimed composition and thus has not been afforded patentable significance.

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Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Liao et al. (U.S. Patent No. 5,605,929). See column 4, lines 35-36, Table 10 at column 44 and Example 10 at columns 44-47.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao et al., as above.

Liao et al. further teach that the catechin compounds may be presented in other formulations that are capable of delivering the compounds systemically, i.e., tablets, capsules, troches, pills syrups and elixirs (column 17, lines 25-45) as well as topically, i.e., creams, lotions, solutions (column 18, lines 62+).

The differences between the above and applicants' claimed subject matter lie in that Liao et al. fail to highlight:

(1) a suppository or ointment dosage form; and

(2) the claim specified ingredient amounts.

However, to the skilled artisan, applicants' claimed subject matter would have been obvious because:

(1) suppositories and ointments were well known the skilled artisan as pharmaceutically acceptable dosage forms capable of delivering active agents systemically and topically, respectively. The selection of any particular dosage form from those known to the skilled artisan would have been a matter well within the purview of the skilled artisan.

(2) At column 17, lines 19-24, the patentees teach that the compositions may conveniently contain 100% active agent, but may be varied. Since pharmaceutical formulations commonly contain a larger proportion of carrier than active ingredient, it is not believed that applicant's required proportion of 5-20% by weight is inconsistent with the patentees' teaching. Also, the determination of the optimum dosage to employ would have been a matter well within the purview of the skilled artisan.

None of the claims are allowed.

The references cited on the attached form PTO-892 and not relied upon are included to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1200

Henley; rjh
September 8, 1997